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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,953	02/09/2004	Robert W. Brocia	527832000420	1280

25225 7590 09/12/2006

MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
SUITE 100  
SAN DIEGO, CA 92130-2040

EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1655

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/775,953	<b>Applicant(s)</b> BROCIA, ROBERT W.	
	<b>Examiner</b> Ralph Gitomer	<b>Art Unit</b> 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

The amendment received 7/12/06 has been entered and claims 1-7 are currently pending in this application.

In view of the amendments to the claims and arguments presented, the rejection of record under 35 USC 112, first paragraph, is hereby withdrawn.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris.

Morris (5,173,434) entitled "Measurement of Color Reactions by Monitoring a Change of Fluorescence" teaches in column 2 last paragraph, fluorescence quenching is described for fluorogenic substrates for assaying enzymes. The synthetic substrate contains a quenching and fluorescing group which is generated. In column 4 line 24 the assay detects the concentration of substances in a colorimetric, turbidimetric or nephelometric reaction with a reader. In column 5 first full paragraph, chromogenic reagents are disclosed which have an absorption spectrum that overlaps the spectrum of a fluorophore. See the claims.

All the features of the claims are taught by Morris for the same function as claimed.

Applicant's arguments filed 7/12/06 have been fully considered but they are not persuasive.

Applicant argues that the present invention includes the light emitting moiety is in the reaction mixture, not separate from the reaction mixture, which is more convenient and has greater sensitivity.

In paragraph 12 as well as others in the present specification, the claimed method is compared to other methods and found to be more sensitive. However, it is the examiner's position that these comparisons are unrelated to the above issue where the indicator is included in the reaction mixture or is in some fashion separated from the reaction mixture until the two are contacted and reacted together which must occur for the indicator to work.

Morris teaches in column 2 last paragraph bridging to all of column 3 as background, standard methods of assaying enzymes by quenching where the indicator is not bound but is in the assay mixture. In column 3 lines 49-53, when the fluorophore is in solution, less than accurate measure of absorbance may be obtained because light is absorbed exponentially through the chromophore sample. The explanation goes on to discuss fluorometric assay sensitivity as related to light detecting. Not as background but the invention of Morris is directed to more direct measuring of the indicator.

Regarding the argument related to advantages of the presently claimed invention, an undisclosed advantage is given little or no weight. No discussion of the advantage of separating the indicator is found in the specification as originally filed.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in all occurrences.

The claims must be carefully rewritten in accordance with standard US patent practice. There are many instances of lack of antecedent basis in the claims, for example in claim 1 line 1, "the concentration".

In claim 1 "if needed" is unclear as to when it would be needed. Claim 1 is an incomplete method claim where standard method steps may include contacting, determining, correlating. It is not seen how the indicator could be present in proportion to the concentration of analyte if the concentration of analyte is unknown. Claim 7 is in improper Jepsen format. And claim 7 is not understood as to what the mixture may be or how the fluorescence is diminished. In claim 11 "the light" lacks antecedent basis.

The disclosure is objected to because of the following informalities:

The specification is objected to because it does not contain the standard headings and sections. Appropriate correction is required.

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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